EIZO

JUN - 8 2011 K103724

Eizo GmbH, Siemensallee 84, 76187 Karlsruhe

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-401)
9200 Corporate Blvd.
Rockville, MD, USA
20850

Name Guenter Michael Volz
Department RD

Telephone +49 (721) 20321-282
Fax +49 (721) 20321-478
E-Mail guenter.volz@eizo.com

Date Nov 30, 2010

Abbreviated 510(k) Summary (in accordance with 21 CFR 807.92)

1. **Date of Summary**
   Nov 30, 2010

2. **Company**
   EIZO GmbH
   Siemensallee 84
   D-76187 Karlsruhe, Germany

3. **Authorized Contact Person**
   Guenter Michael Volz

4. **Device Information**
   - Trade Name/Model: 6GF6201-8C$## (where $ = A-Z and # = 0-9)
   - Common Name: Display, 10MP Grayscale Flat Panel Display, GX1030
   - Classification Name: System, Image Processing
   - Classification Number: 21 CFR 892.2050, Product Code LLZ

5. **Predicate Device**
   - Coronis Fusion 10MP (MDCG-10130) (K093197)

6. **Device Description**
The 6GF6201-8C$## is a diagnostic 10MP grayscale flat panel display for viewing medical images. With the calibrated gamma response stored in five internal lookup tables, the display is suitable for use with a wide range of DVI graphic controller boards. The display is used in dual-head configuration.

7. **Intended Use**
The 10MP Grayscale Flat Panel Display is intended to be used in displaying and viewing digital images, including digital mammography, for review and analysis by trained medical practitioners.

8. **Technological Characteristics**
The 10MP Grayscale Flat Panel Display uses a monochrome LCD panel employing in-plane switching (IPS) technology to allow wide viewing angles. It has a resolution of 4096 x 2560 pixels and is used in landscape mode. The display uses backlight sensor to automatically stabilize the set luminance levels of the CCFL backlight over time. It also sports an integrated front sensor for independent grayscale

verification. The factory calibrated gamma response is stored in five lookup tables located in the display, allowing users to adapt the display to local lighting conditions and ensuring that the display function is DICOM compliant regardless of the display controller used.

The 10MP Grayscale Flat Panel Display may be offered in different housing colors and with different logos. These cosmetic differences are reflected in the designators represented by the characters "$" and "#" included in the model trade name 6GF6201-8C$##, where $ represents a letter between A and Z, and # is a number between 0 and 9.

The 10MP Grayscale Flat Panel Display uses the same LCD panel from the same manufactorer as the predicate device and employs CCFL backlight technology. It is equipped with two integrated luminance sensors, one mounted rear center and a built in front sensor, as included with the Coronis Fusion 10MP.

The housing, stand, electronics and the integrated luminance sensors are not the same as those components used in the predicate devices. The overall design of the 6GF6201-8C$## was validated in accordance with internationally recognized safety and EMC standards by independent testing facilities and inhouse. Additionally, EIZO GmbH performed a range of system and performance tests to ensure that the 10MP Grayscale Flat Panel Display performed in accordance with its specifications.
A more detailed description is included in section 09 "Declaration of Conformity or Summary Report".
The "Guidance for Industry: Guidance for the Submission Of Premarket Notifications for Medical Image Management Devices" applies to this abbreviated 510(k) submission.
None of the tests revealed behaviors inconsistent with the expected performance of a 10MP grayscale flat panel display.

While the predicate device is equipped with a proprietary high speed display controller, the 6GF6201-8C$## was designed to receive and display images from standard, commercial DVI display controllers.

9. Conclusion

The 10MP Grayscale Flat Panel Display is substantially equivalent to the predicate device with respect to technical characteristics, application and intended use. Major components are the same, and those that are different have been validated, both in independent testing and internal performance tests. Any differences between the devices do not affect safety or effectiveness.

The 510(k) Premarket Notification for the 6GF6201-8C$## contains sufficient information and data to enable FDA - CDRH to determine substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Günter M. Volz
Project Manager
EIZO GmbH
Siemensallee 84.
D-76187 Karlsruhe
GERMANY

JUN - 8 2011

Re: K103724
Trade/Device Name: 10 MP Grayscale Flat Panel Display (GX1030)
Model: 6GF6201-8C$## (where $ = A-Z and # = 0-9)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 21, 2011
Received: May 3, 2011

Dear Mr. Volz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103724

Device Name: 10MP Grayscale Flat Panel Display (GX1030)
Model: 6GF6201-8C$## (where $ = A-Z and # = 0-9)

Indications For Use: The 10MP Grayscale Flat Panel Display (GX1030) is intended to be used in displaying and viewing digital images, including digital mammography, for review and analysis by trained medical practitioners.

Prescription Use ___Yes___ AND/OR Over-The-Counter Use ___No___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103724